

comprising administering to the subject, or delivering to the subject's tissues, an effective amount of the pharmaceutical composition of claim 38.

51. The method of claim 50, wherein the androgen responsive disease is selected from the group consisting of prostate cancer, benign prostatic hyperplasia, breast cancer, alopecia, acne, hypogonadism and hirsutism.

52. (New) The method of any one of claims 40 to 51, wherein the subject is a human.

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REMARKS

The instant invention is drawn, *inter alia*, to methods for treating androgen responsive conditions.

The previously pending claims 11-32 have been cancelled without prejudice to future prosecution. The new claims 33 to 52 are supported in the specification and claims as filed and add no new matter. See, for example, the compound of formula 1 described on pages 3-4, and the Examples described on pages 77 to 81.

The rejections from the Final Office Action will be discussed to the extent that they can be applied to the new claims.

*Claim Rejections - 35 U.S.C. § 112, first paragraph*

Cancelled claims 11 to 32 stood rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement for the reasons previously stated in the Office Action, dated February 5, 2002. Briefly, the Examiner alleged that although the specification is enabling for the treatment of androgen responsive disease, it was not enabling for the prevention of androgen responsive disease. This rejection was traversed in the prior Response to Office Action, dated August 13, 2002.

The traversal argument was laid out in approximately one and a half pages of the Response (pages 34-35). However, there was an inadvertent omission of the word "not" in the following sentence, "Since the claimed methods are sufficient to treat the diseases, there is no basis to assert that those methods are not sufficient to prevent the same diseases" (page 35, lines 9-11).

Unfortunately, this typographical error resulted in the Examiner's conclusion that, "Applicants admit on page 35, lines 9-11 of their response that since the claimed methods are sufficient to treat the diseases, there is no basis to assert that those methods are sufficient to prevent the same diseases" (page 2, lines 5-7).

In order to facilitate the analysis of Applicants previous response to this rejection, the prior traversal argument has been reproduced below with the offending sentence corrected.

"To establish and maintain a rejection under 35 U.S.C. §112, first paragraph, the Office must provide logical reasoning to support its position. The Office must "explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." *In re Marzocchi and Horton*, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971). The Office must advance "substantive reasons why the instant specification is non-enabling." "Mere broad generalizations and allegations are insufficient for holding of non-enablement." *Ex parte Goeddel* 5 U.S.P.Q. 2d 1449 (B.P.A.I. 1987). As explained below, Applicants respectfully submit that the rejection is improperly based on a broad allegation, which the Office does not support.

In casting the rejection, the Office did not explain why the present specification, which the Office conceded was enabled for the treatment of androgen responsive diseases, did not teach how to prevent the development of those diseases. Since the claimed methods are sufficient to treat the diseases, there is no basis to assert that those methods are **not** sufficient to prevent

the same diseases. Even if a single normal cell were to give rise to two cells capable of causing an androgen responsive disease if they could proliferate, administration of the compound would inhibit further growth, which would prevent disease. Obviously, an androgen driven disease does not arise in a single step or event as a full blown pathological condition in a single day. Such diseases start from a single cell or a limited number of cells, which develop over time to detectable disease.

Applicants also note that humans and animals are believed to spontaneously generate malignant and other abnormal cells throughout their life span. However, immune surveillance and other defense mechanisms usually eliminate these cells before they proliferate to detectable levels or cause any detectable disease. Such humans or animals are not considered to be diseased unless and until there has been sufficient cell proliferation to cause a detectable pathology or symptom. Thus, since the claimed methods provide a means to treat the diseases, they will also prevent the diseases by blocking the proliferation needed to cause them.

The discussion above is a rationale that supports Applicant's position that the claimed methods would prevent androgen driven conditions. In view of the foregoing, Applicants respectfully submit that the specification lacks no essential teaching of how to use the claimed invention to prevent the diseases. The rejection does not contain a reasoned argument by the Office to support an allegation of non-enablement and Applicants have provided a logical argument that supports enablement. The rejection should thus be withdrawn. *In re Marzocchi and Horton, supra, Ex parte Goeddel, supra.* Applicants request reconsideration and withdrawal of the rejection."

*Claim Rejections - 35 U.S.C. § 112, second paragraph*

Cancelled claims 19, 21, 22 and 24 stood rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. Although these rejections are moot in light of the currently

pending claims, they will be briefly addressed for completeness and ease of future prosecution.

Claims 19 & 21: Antecedent Basis

The Examiner asserts that there is no antecedent basis in claim 11 for the additional compounds encompassed by claims 19 and 21. Applicant respectfully traverses this rejection.

It is respectfully submitted that the additional compounds encompassed by claims 19 and 21 do not refer back to claim 11 and therefore do not require antecedent basis in claim 11. They are compounds to be administered in addition to the "compound of formula 1 or 2" from claim 11.

In view of the above, Applicant respectfully requests that this rejection under 35 U.S.C. §112, second paragraph be withdrawn.

Claim 22: The Term "Comprises"

The Examiner asserted that it is improper to use the term "comprises" in cancelled claim 22 with respect to a compound because it allegedly left the structural formula of the compound open-ended. Applicant respectfully traverses this rejection.

Cancelled claim 22 was dependent on cancelled claim 11 in which the formulas for the compounds were delimited. Cancelled claim 22 simply identified a subset of the compounds in cancelled claim 11 by requiring that 1, 2, 3, 4, 5, or 6 of the total possible moieties in the formulas was selected from the group described in the claim. That leaves all the other moieties in the formulas to be anything else permitted under cancelled claim 11.

Claim 24: Compound Limitations

The Examiner asserted that it is not clear whether the compounds of cancelled claim 24 were limited to the specific compounds set forth or if they encompassed all the compounds of formula 1. This rejection is moot.

Claim 24: Compound Naming

The Examiner asserted that the names of the compounds set forth in cancelled claim 24 were not art recognized. Applicant respectfully traverses this rejection.

The courts have imposed no requirement that terms must be "art recognized" to afford sufficient clarity for patent claims. In fact, the court has written, "It is black letter law that a patentee can choose to be his or her own lexicographer by clearly setting forth an explicit definition for a claim term that could differ in scope from that which would be afforded by its ordinary meaning." *Rexnord Corp. v Laitram Corp.*, 274 F.3d 1336, 1342, 60 U.S.P.Q.2d 1851, 1854 (Fed. Cir. 2001).

In *Teleflex, Inc. v Ficosa North American Corp. et al.* 299 F.3d 1313, 63 U.S.P.Q.2d 1374 (Fed. Cir. 2002) the court wrote, "For example, an inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention with reasonable clarity, deliberateness, and precision." Citing *In re Paulsen*, 30 F.3d 1475, 1480, 31 U.S.P.Q.2d 1671, 1674 (Fed. Cir. 1994). In *Jack Guttman, Inc. v Kopykake Enterprises, Inc.*, 302 F.3d 1352 (Fed. Cir. 2002) the court wrote, "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." Citing *Vitrionics Corp. v Conceptronic, Inc.*, 90 F.3d 1576, 1582, 39 U.S.P.Q.2d 1573, 1577 (Fed. Cir. 1996). None of these decisions require an "art recognized" term in order to adequately define the subject matter of an invention.

Applicants claim terminology is clear and precise as required by the courts. Further, this claim terminology has been used previously in other issued U.S. Patents. The Examiner's attention is drawn to the claims of issued U.S. Patent Serial Number 5,798,340 (newly cited) in which this manner of naming compounds is used.

*Claim Rejections - 35 U.S.C. § 102(b)*

Cancelled claims 11 to 32 stood rejected under 35 U.S.C. § 102(b) for alleged anticipation by Blohm, et al. (U.S. Patent No. 5,075,464). The Examiner stated that Blohm, et al. "disclose the use of androstene derivatives for the treatment of androgen-related disorders." This rejection is respectfully traversed as it applies to the pending claims.

The examiner has failed to establish anticipation of the instant invention. To anticipate, the reference must teach every element of the claims. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987).

The instant invention is drawn, *inter alia*, to the treatment of androgen responsive diseases with compounds that do not include 17 $\beta$ -(cyclo-propylamino)androstene derivatives. In contrast, the Blohm reference teaches the use of 17 $\beta$ -(cyclo-propylamino)androstene derivatives (not the compounds of the instant invention) to treat androgen-dependent disorders. Therefore, every element of the instant claims is not found in the Blohm reference and this rejection is inappropriate.

In view of the above, Applicant respectfully requests that the rejection for anticipation under 35 U.S.C. 102(b) be withdrawn.

*Claim Rejections - 35 U.S.C. § 103(a)*

Cancelled claims 11 to 32 stood rejected under 35 U.S.C. § 103(a) for alleged obviousness over Blohm, et al. (U.S. Patent No. 5,075,464). The Examiner stated that Blohm, et al. "disclose the use of androstene derivatives for the treatment of androgen-related disorders...In addition, if there are any differences between the claimed methods and the prior art method, the differences would appear to be minor in nature and the claimed

methods, which fall within the scope of the prior art's disclosure would have been *prima facie* obvious..." This rejection is respectfully traversed as it applies to the pending claims.

The Examiner has failed to establish a *prima facie* case of obviousness. Three basic criteria must be met: 1) some suggestion or motivation to combine reference teachings; 2) a reasonable expectation of success; and 3) the references must teach or suggest all the claim limitations (see, *In re Vaeck*, 947 F.2d 488, 20U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

"The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness." M.P.E.P. 2142 "Legal Concept of *Prima Facie* Obviousness". "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Inter. 1985). This the Examiner has not done. No facts in support of the conclusion of *Prima facie* obviousness have been provided, nor was any "convincing line of reasoning". See also, *In re Sang Su Lee*, 277 F.3d 1338; 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002).

In view of the above, Applicant respectfully requests that the rejection for alleged obviousness under 35 U.S.C. 103(a) be withdrawn.

#### Summary

Applicant asserts that the claimed invention is in condition for allowance and notification to that effect is respectfully requested. In order to facilitate the rapid allowance of the invention, the Examiner is encouraged to call the undersigned at the number below.

Any fees due in relation to the timely filing of this Response are hereby authorized to be deducted from Deposit Account No. 501536.

Respectfully submitted,

Date: *April 17, 2003*

By: *Heather L. Callahan*  
Heather L. Callahan  
Registration No. 43,524

Hollis-Eden Pharmaceuticals, Inc.  
4435 Eastgate Mall, Suite 400  
San Diego, CA 92121  
Office: (858) 587-9333  
Direct: (858) 320-2578